

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION**

HILL-ROM COMPANY, INC.,)	
HILL-ROM SERVICES, INC., and)	
HILL-ROM MANUFACTURING, INC.)	
)	
Plaintiffs,)	
v.)	
)	Case No. 2:14-cv-187
GENERAL ELECTRIC COMPANY,)	
)	
Defendant.)	
)	

**MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS'
MOTION FOR PRELIMINARY INJUNCTION**

INTRODUCTION AND FACTUAL BACKGROUND

Plaintiffs Hill-Rom Company, Inc., Hill-Rom Services, Inc., and Hill-Rom Manufacturing, Inc. (collectively, “Hill-Rom”) seek a preliminary injunction to enjoin Defendant General Electric Company (“GE”) from its continued infringement of Hill-Rom’s patents. The patents¹ cover technology that decreases dramatically the number of patients catching infections while staying in hospitals or other healthcare facilities. Hill-Rom’s inventions use real-time locating systems (“RTLS”) to ensure that healthcare workers sanitize their hands when required, thereby greatly reducing the risks of transmitting infections between patients. Hill-Rom pioneered this hand hygiene technology over 15 years ago, patented it, and recently introduced it into the marketplace. Despite having actual knowledge of Hill-Rom’s patents since at least 2012, GE recently began selling a system based on Hill-Rom’s technology. GE’s system includes each element of the patent claims that Hill-Rom asserts.

¹ U.S. Patent No. 6,727,818 (“the ’818 patent”), U.S. Patent No. 8,368,544 (“the ’544 patent”), and U.S. Patent No. 7,408,470 (“the ’470 patent” and, collectively with the ’818 patent and the ’544 patent, “patents in suit”).

Because the market for this technology is in now in an early, critical phase during which competitors' long-term market positions will be determined, Hill-Rom is suffering and stands to suffer additional incalculable and irreparable harm, including substantial long-term market loss in this nascent market, price erosion, and loss of good will, reputation, and customer relations, if GE's infringement is allowed to continue unabated pending this litigation. Hill-Rom's motion for a preliminary injunction is based on this memorandum, as well as the declarations of Robin A. Felder, Ph.D, an expert in medical automation at University of Virginia ("Felder Decl."); Bradley N. Reiff, Ph.D, an expert economist at Compass Lexecon ("Reiff Decl."); and Timothy Wildman ("Wildman Decl.") and Adam McMullin ("McMullin Decl.") of Hill-Rom.

The Problem: HAIs are Killing People and Costing Billions

Infections that patients catch in hospitals, known as healthcare-associated infections ("HAIs"), affect approximately 1 in 20 persons admitted to a hospital in the United States – and impose costs in the tens of billions of dollars annually. *See R. Douglas Scott II, The Direct Medical Costs Of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention* (March 2009) at 1, http://www.cdc.gov/HAI/pdfs/hai/Scott_CostPaper.pdf (last accessed May 7, 2014) (HAIs are estimated to affect 4.5 out of every 100 persons admitted to a hospital and cost U.S. hospitals from \$28.4 to \$45 billion annually). The human toll can affect any of us—in 2011, approximately 75,000 with HAIs died during their hospitalizations. **HEALTHCARE-ASSOCIATED INFECTIONS (HAIs)**, <http://www.cdc.gov/HAI/surveillance/index.html> (last accessed May 7, 2014). The financial costs hit hospitals' bottom lines due to legislation requiring hospitals to bear the full costs of treating such infections. Reiff Decl. at ¶ 14. Yet reducing HAIs has proved stubbornly difficult.

Old Methods to Reduce HAIs Did Not Work

Researchers know that HAIs are often spread on the hands of healthcare workers and that consistent hand sanitization by doctors, nurses, and other hospital staff can significantly reduce the number of HAIs. McMullin Decl. at ¶¶ 2, 3. Yet healthcare workers are busy, and in the fast-paced, often chaotic environment of a hospital, hand hygiene compliance rates remain too low, and inconsistent. *See* Wildman Decl. at ¶ 5. Until now, there has been no reliable way to ensure that healthcare workers are sanitizing their hands when they should be. In the past, hospitals tried using human monitors to manually record handwashing events, but researchers found that hand hygiene compliance lapsed when the human monitor was no longer present. *See Id.* This approach proved ineffective.

Hill-Rom Invents Technology That Significantly Reduces HAIs

Hill-Rom recognized this problem long ago, and over the past 15 years has worked to develop and refine the first technology that can objectively, automatically, and in real time track healthcare workers' compliance with hand hygiene requirements. *See* Wildman Decl. at ¶¶ 6-7. That research has resulted in a patent family encompassing breakthrough technology that uses RTLS to automate monitoring of hand hygiene compliance. *Id.* The claims of Hill-Rom's '818 and '544 patents are directed to systems and methods for monitoring hand hygiene compliance, and the '470 patent claims are directed to a computer readable medium storing a computer program with instructions for monitoring hand hygiene compliance. Felder Decl. at ¶ 14.

The significance of Hill-Rom's technology is difficult to overstate: Hill-Rom's patented, automated hand hygiene technology solves the problems that plagued early attempts to enforce compliance through manual monitoring. Wildman Decl. at ¶¶ 5-6. Better hand hygiene

compliance translates to human lives saved and significant budgetary relief for hospitals. McMullin Decl. at ¶ 3. To invoke a cliché, Hill-Rom’s patented technology is a game-changer.

The Market for Effective Hand Hygiene Technology Is Huge

Because of the huge potential savings to healthcare facilities, and the immeasurable benefit of fewer lives lost, the potential market for this technology is massive. There are over 5,000 hospitals in the United States – all potential customers. Reiff Decl. at ¶ 25. RTLS-based hand hygiene systems only just became available commercially in approximately late 2012. McMullin Decl. at ¶ 15. Although the RTLS-based hand hygiene market is nascent, with estimated sales of approximately \$5 million in 2013, the size of the market is increasing rapidly. *Id.* at ¶¶ 16, 18. For these reasons, in addition to being a boon to society, Hill-Rom’s pioneering hand hygiene technology has the potential to amplify Hill-Rom’s financial performance and greatly augment its favorable reputation and good will for years to come. McMullin Decl. at ¶¶ 18-20, 43-48.

The Wide-Open Market for Hill-Rom’s Inventions Attracts an Infringer

Recognizing the potential of this technology, GE developed an RTLS-based hand hygiene compliance product, called AgileTrac, which is based on Hill-Rom’s hand hygiene technology and blatantly infringes Hill-Rom’s patents. *See* Wildman Decl. at ¶ 35; Felder Decl. at ¶¶ 49, 64, 78. Despite knowing of Hill-Rom’s patents, GE has forged ahead with its infringement unabated.

GE Targets HCA, One of the Most Significant Customers in the Market

Though GE’s hand hygiene systems at issue here are a small part of, and recent addition to, GE’s vast product lines, it is pushing to sell AgileTrac to one of the largest hospital chains in America, Hospital Corporation of America (“HCA”). McMullin Decl. at ¶¶ 13, 21, 30-31, 35.

HCA has already installed GE's AgileTrac in at least one of its nearly 300 healthcare facilities, and GE is striving to become its exclusive supplier of RTLS-based hand hygiene systems – systems invented and patented by Hill-Rom. *Id.* at ¶ 35. Hill-Rom has learned that HCA will purchase RTLS-based hand hygiene systems for its many hospitals from either Hill-Rom or GE. *Id.* at ¶ 29. Thus, Hill-Rom and GE are competing head-to-head in an emerging market for hand hygiene systems, including for the single most significant customer. *Id.* at ¶ 30.

The hand hygiene provider that wins HCA as a client will have an overwhelming advantage in the market, not only because HCA's decision to purchase from a particular supplier will cover a large network of hospitals, but also because that decision will confer a reputational advantage on that supplier and other customers will be more likely to purchase from it as well. Reiff Decl. at ¶¶ 30-31. To invoke another cliché, Hill-Rom will never again get this chance to make an important first impression on this nascent market.

Hill-Rom is informed that GE has installed at least one AgileTrac infringing system at an HCA facility in Summerville, South Carolina and installed another approximately five AgileTrac hand hygiene systems elsewhere. McMullin Decl. at ¶¶ 35-36. Hill-Rom itself has sold and installed several hand hygiene systems in the United States. *Id.* at ¶ 37.

Without a Preliminary Injunction, Hill-Rom Faces Irreparable Harm

This is a critical time in the market for RTLS-based hand hygiene compliance technology, and due to the nature of the technology, early sales hold special significance. The RTLS-based hand hygiene systems at issue here require a meaningful investment in infrastructure. *See* Felder Decl. at ¶ 13; Wildman Decl. at ¶ 6. Real time tracking requires each facility to be equipped with room location devices, soap dispensers, and other equipment usually installed within ceilings and walls that receive and transmit signals. Felder Decl. at ¶ 13;

Wildman Decl. at ¶¶ 6, 12, 18, 26. Due to the significant investment and infrastructure required for each system, a customer is likely to remain committed to a provider for as many as 15 years, and it would be extremely difficult for a competitor to dislodge an incumbent supplier. Reiff Decl. at ¶¶ 27-29. The company that first sells a hand hygiene system to a customer also has additional advantages over competitors. *Id.* at ¶ 29. For example, it will establish a relationship with the customer during the years following the sale, as it provides customer support and maintenance of the system it sold. *Id.* Through these ongoing contacts, the customer relationship is likely to be strengthened. *Id.*

By losing both initial sales and ultimate market share to GE, Hill-Rom will lose not only the profits from the lost sales and likely future sales to that customer, but Hill-Rom is also likely to suffer damage to its brand and reputation. *Id.* at ¶ 32. With a diminished market share, Hill-Rom is less likely to be perceived as the pioneering developer and leading manufacturer of hand hygiene systems that it is. *Id.* In addition, GE's infringement potentially limits the price Hill-Rom can charge for its product, causing significant price erosion. *Id.* at ¶ 30 n.25, ¶ 38. Thus, not only will Hill-Rom suffer lost sales, but it may have made those sales at a higher price absent GE's infringement. *See id.*

In sum, GE's infringement of Hill-Rom's patents irreparably damages Hill-Rom in the market, unfairly captures lasting market share, deprives Hill-Rom of valuable customer relationships, and erodes the price Hill-Rom can charge for its product. As discussed below, a preliminary injunction is proper and necessary to preserve the status quo and prevent this wrongful and imminent injury.

DISCUSSION

The Patent Act protects a patent owner's rights in its invention by giving courts the ability to preliminarily enjoin infringers "to prevent the violation of any right secured by patent,

on such terms as the court deems reasonable.” 35 U.S.C. § 283. In deciding whether to issue a preliminary injunction, a court must consider whether the patentee has shown “(1) likelihood of success on the merits, (2) irreparable harm, (3) balance of hardships, and (4) public interest.” *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 926 (Fed. Cir. 2012).² To obtain a preliminary injunction, “the movant must establish at the very least both of the first two factors, *i.e.*, a likelihood of success on the merits and irreparable harm.” *Anton/Bauer, Inc. v. PAG, Ltd.*, 329 F.3d 1343, 1348 (Fed. Cir. 2003). *See also Kemin Foods, L.C. v. Pigmentos Vegetales del Centro S.A. de C.V.*, 93 F. App’x 225, 229 (Fed. Cir. 2004) (same).

Here, each of the factors strongly weighs in favor of this Court issuing a preliminary injunction prohibiting GE from continuing to infringe Hill-Rom’s patents.

I. HILL-ROM IS LIKELY TO SUCCEED ON THE MERITS OF ITS PATENT INFRINGEMENT CLAIM.

To show a reasonable likelihood of success on the merits, the patentee must demonstrate that (1) it will likely prove infringement, and (2) its infringement claim will likely withstand challenges to validity and enforceability of the asserted patents. *See Purdue Pharma L.P. v. Boehringer Ingelheim GMBH*, 237 F.3d 1359, 1363 (Fed. Cir. 2001). The grant of a preliminary injunction does not require that infringement be proved beyond all question, or that there be no evidence supporting the viewpoint of the accused infringer. *H.H. Robertson, Co. v. United Steel Deck, Inc.*, 820 F.2d 384, 390 (Fed. Cir. 1987), *abrogated on other grounds by Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995). Nor is the patentee required to show

² Because “a preliminary injunction of this type . . . involves substantive matters unique to patent law,” a court addressing a motion for preliminary injunction in a patent case must apply the law of the Federal Circuit. *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 n.12 (Fed. Cir. 1988). “[P]urely procedural questions,” however, “involving the grant of a preliminary injunction are controlled by the law of the appropriate regional circuit.” *Id.*

infringement of all claims; rather, the patentee must show merely that it will likely prove infringement of any one claim. *Intervet Am., Inc. v. Kee-Vet Labs., Inc.*, 887 F.2d 1050, 1055 (Fed. Cir. 1989).

At trial, the patentee need only establish infringement by a preponderance of the evidence. *See, e.g., Braun Inc. v. Dynamics Corp. of Am.*, 975 F.2d 815, 819 (Fed. Cir. 1992). If each element recited in the claims is found in an accused product, the manufacturer of the accused product cannot avoid infringement merely by identifying additional elements. *Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1178 (Fed. Cir. 1991). Likewise, an accused method “does not avoid literally infringing a method claim . . . simply because it employs additional steps.” *Dow Chem. Co. v. Sumitomo Chem. Co., Ltd.*, 257 F.3d 1364, 1380 (Fed. Cir. 2001).

“[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States’ infringes the patent.” *Rotec Indus., Inc. v. Mitsubishi Corp.*, 215 F.3d 1246, 1251 (Fed. Cir. 2000) (citing 35 U.S.C. § 271(a)). An infringement analysis involves two steps: first the claims must be construed to determine the scope of the claims, and then the claim elements must be compared to the accused device or process. *Zodiac Pool Care Inc. v. Hoffinger Industries, Inc.*, 206 F.3d 1408, 1413 (Fed. Cir. 2000). In making this comparison, the trier of fact must compare the accused product with the claims of the patent only, and not with the patentee’s commercial embodiment or other version of the patent. *Zenith Laboratories, Inc. v. Bristol-Myers Squibb Company*, 19 F. 3d 1418, 1423 (Fed. Cir. 1994). However, in applying the claims to the accused product, the Court need not issue a final claim construction at the preliminary injunction phase. The Court is free to revisit and adjust its interpretation of the claim terms “as its understanding of the technology evolves.” *See Jack Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1361 (Fed. Cir. 2002).

Infringement under the doctrine of equivalents proceeds in much the same way.³ A system may infringe under the doctrine of equivalents when there is no substantial difference between the claimed invention and the accused product. *See CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1365 (Fed. Cir. 2002); *Netword, LLC v. Central Corp.*, 242 F.3d 1347, 1350 (Fed. Cir. 2001); *Wang Labs, Inc. v. America Online, Inc.*, 197 F.3d 1377, 1386 (Fed. Cir. 1999).

A. GE's RTLS-Based Hand Hygiene Product Infringes the '818, '544, and '470 Patents.

The publicly available marketing materials and an inspection of the GE system presently installed at HCA's Summerville Medical Center leave no doubt that the GE system infringes and that GE is inducing customers to infringe the method claims in the patents in suit. Felder Decl. at ¶¶ 49, 64, 78. As set forth below and in the supporting declarations filed herewith, each claim element and step of multiple claims of the patents in suit is found in GE's products and conduct. *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1301 (Fed. Cir. 2011).

1. Overview of GE's Infringement

As described in more detail in the declarations of Robin A. Felder, Ph.D. and Timothy Wildman, Hill-Rom is likely to prove that GE's AgileTrac hand hygiene system infringes at least claims 1-3, 6, 12-15, 37, 43-45, 47-48, 52, and 56 of the '818 patent, at least claims 1, 5, and 13-14 of the '544 patent, and at least claims 15-16 and 19 of the '470 patent. GE infringes Hill-Rom's patents both directly and indirectly.

³ Hill-Rom addresses literal infringement in this brief, but reserves the right to establish infringement under the doctrine of equivalents as the case proceeds.

2. GE's Manufacture, Marketing, and Sales Infringe the Asserted Patents Directly.

Hill-Rom is likely to prove that GE directly infringes at least claims 1-3, 6, 12-15, 37, 43-45, 47-48, 52, and 56 of the '818 patent ("the '818 Asserted Claims"), at least claims 1, 5, and 13-14 of the '544 patent ("the '544 Asserted Claims"), and at least claims 15-16 and 19 of the '470 patent ("the '470 Asserted Claims").

(a) '818 Patent

The '818 Asserted Claims are directed to systems and methods for monitoring compliance with a hand hygiene protocol. Of the method claims, claims 1-3, 6, and 12-15 each require the following steps:

(1) receiving first location information which tracks movement of a person through a facility and (2) handwashing information associated with attempts by the person to wash her hands; (3) determining, based upon the first location information and the handwashing information received during the receiving step, whether a person who has entered a patient contact zone has washed her hands since her most recent exposure to a contamination zone other than her current exposure to the patient contact zone; and (4) updating compliance information for the person based upon the determining step.

The GE system performs each step of these method claims. The GE software receives information from a series of room locators about the location of a caregiver as he or she moves throughout the hospital; receives handwashing information from a handwashing monitoring sensor; determines whether a caregiver has washed his or her hands since entering a patient room; and updates compliance information for that caregiver. Felder Decl. at ¶¶ 22-25. Method claim 37 is similarly infringed, as described in further detail in the supporting declaration. *Id.* at ¶¶ 33-36.

The system claims of the '818 patent, claims 43-45, 47-48, and 56, each require (1) a master station; (2) a plurality of first sensors operable to track movement of a person through a

facility, and provide the master station with location information associated with the movement of the person; and (3) a plurality of second sensors operable to provide the master station with handwashing information associated with attempts by the person to wash her hands. The master station is operable to

(1) determine based upon the location information whether the person has entered a patient contact zone, (2) determine based upon the location information and the handwashing information whether the person washed her hands since her most recent exposure to a contamination zone other than her current exposure to the patient contact zone, and (3) update compliance information for the person based upon whether the person has entered a patient contact zone and whether the person washed her hands since her most recent exposure to a contamination zone other than her current exposure to the patient contact zone.

The GE system infringes the system claims of the '818 patent because, among other things, the GE system has a master station with software that determines whether someone has entered a patient room and whether the person has washed his or her hands within a preset period of time, and updates information about the caregiver's compliance. Felder Decl. at ¶¶ 37-49. The GE system has readers located throughout the facility that contain sensors to receive location information as a person moves through the facility. The system also has sensors that are wired to each soap or alcohol dispenser to track handwashing attempts by a person.

(b) '544 Patent

The '544 Asserted Claims are directed to systems for monitoring compliance with a hand hygiene protocol. The asserted independent claim requires

(1) a sensor associated with a handwashing device positioned in a facility and configured to detect the presence of a person in a handwashing monitoring area, (2) a badge configured to transmit an identification signal to the sensor, the identification signal being associated with a person, (3) a handwashing monitoring device operably coupled to the handwashing device, the handwashing monitoring device being configured to generate a compliance signal indicative of whether the person has or has not used the

handwashing device, (4) a network, the sensor and the handwashing device being operably coupled to the network, and

(5) a master station operably coupled to the network, the master station including memory and a processor, the master station being configured to receive via the network a combined signal including information indicating that an identification signal from the badge has been received by the sensor and information indicating that a compliance signal has been generated by the handwashing monitoring device, the master station being configured to determine whether the person is or is not in compliance with a handwashing policy of the facility.

The GE system has each of these elements. The system includes readers located throughout the facility that are sensors to receive handwashing information; badges; a unique identification signal going from the badges to a reader; a handwashing monitoring device; an actuation (compliance) signal from the monitoring device; a hospital network; and a master station containing the GE software that aggregates the compliance information and generates reports of compliance or non-compliance with the facility's hand hygiene policy. Felder Decl. at ¶¶ 68-78.

(c) '470 Patent

The '470 Asserted Claims are directed to computer readable media storing computer programs comprising instructions for monitoring hygiene to

(1) access a predetermined hygiene policy, (2) receive usage information indicative of use of a cleaning device to clean an item, (3) receive identification information uniquely identifying an item, (4) receive location information indicative of a location of an item, (5) receive contact information indicative of an instance of contact between a first item and a second item, (6) evaluate the usage information, identification information, location information, and contact information to detect compliance or non-compliance with the hygiene policy, and (7) generate an output indicative of such compliance or non-compliance.

The GE software performs each of the steps listed in the '470 Asserted Claims and thus is likely to contain the computer readable media claimed in the '470 Patent. The GE software accesses a hygiene policy of a facility; receives information about the usage of a soap or alcohol

dispenser; receives information identifying a particular caregiver from a badge; receives information about the location of the caregiver from a room locator; receives information about the caregiver's contact with a cleaning device when the caregiver actuates the dispenser; evaluates the information to determine compliance or non-compliance with the facility's hand hygiene policy; and generates a report of compliance or non-compliance with the facility's policy. Felder Decl. at ¶¶ 52-61.

3. GE's Marketing and Sale of the AgileTrac Hand Hygiene System Constitute Inducement and Contributory Infringement of the Asserted Patents.

Hill-Rom will also prove that GE's activities constitute indirect infringement. First, GE's sales of the system induce its customers to infringe the asserted patents because the customers infringe the asserted method and system claims by using the system as installed. Liability for inducement of infringement under 35 U.S.C. § 271(b) arises when the defendant knew of the patent and it "actively and knowingly aid[ed] and abet[ted] another's direct infringement. *Walter Tech Corp. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988) (emphasis omitted). The attached supporting materials demonstrate conclusively that GE's system meets each element of the asserted system claims and performs each element of the asserted method claims. Further, GE has had actual knowledge of the '818 and '470 patents since well before this lawsuit. For example, GE cited the patent application that matured into the '470 patent during prosecution of its own patent application in 2012, which has still not issued. During prosecution of that same application, a patent examiner at the U.S. Patent and Trademark Office cited the '818 patent as blocking prior art to GE's claimed invention. GE installed the accused GE systems after these events, and thus copied Hill-Rom's patented technology.

GE also contributes to its customers' infringement of the asserted patents. A party is liable for contributory infringement "if it knows the products [it sells] to be 'especially made or

especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use.”” *RF Delaware, Inc. v. Pac. Keystone Technologies, Inc.*, 326 F.3d 1255, 1267 (Fed. Cir. 2003) (citing 35 U.S.C. § 271(c)).

In the present case, asserted claims 1-3, 6, and 12-15, and 37 of the ’818 patent are directed to a patented process. The GE system is especially adapted for performing these claimed methods of monitoring hygiene compliance; indeed, GE’s marketing materials make clear that the sole purpose of the GE system is as follows: “GE Healthcare’s AgileTrac hand hygiene platform provides the capability to accurately record, measure, and report hand-washing data throughout a patient care facility[.]” Felder Decl., Exh. D at 2. The inescapable conclusion is that GE’s sales of its AgileTrac hand hygiene system constitute contributory infringement.

B. The ’818, ’544, and ’470 Patents Are Valid.

Patents are presumed valid. 35 U.S.C. § 282(a). This presumption exists at every stage of litigation, including the preliminary injunction stage. *Canon Computer Sys., Inc. v. Nu-Kote Int’l, Inc.*, 134 F.3d 1085, 1088 (Fed. Cir. 1998). If GE does not challenge validity, the presumption of validity is sufficient on its own to satisfy Hill-Rom’s burden of showing a likelihood of success on validity issues. *Id.* If GE challenges validity in an attempt to defend against Hill-Rom’s motion, GE must demonstrate by clear and convincing evidence that the patent is invalid. 35 U.S.C. § 282; *Gemmy Indus. Corp. v. Chrisha Creations Ltd.*, 452 F.3d 1353, 1358 (Fed. Cir. 2006). In the preliminary injunction context, this would require that GE “establish a substantial question of invalidity or unenforceability, i.e., that it is likely to succeed in proving invalidity or unenforceability of the asserted patents.” See *Abbott Labs v. Andrx Pharm., Inc.*, 473 F.3d 1196, 1201 (Fed. Cir. 2007). Even if GE can identify some evidence of invalidity, at this stage in the case Hill-Rom is held to a less stringent standard; Hill-Rom need

only show a “clear case supporting the validity of the patent in suit.” *See Abbott Labs. v. Sandoz, Inc.*, 500 F. Supp. 2d 807, 817 (N.D. Ill. 2007).

II. HILL-ROM WILL SUFFER IRREPARABLE HARM IF THE COURT DOES NOT GRANT A PRELIMINARY INJUNCTION.

Irreparable harm “is suffered when monetary damages are difficult to ascertain or are inadequate.” *Multi-Channel TV Cable Co. v. Charlottesville Quality Cable Operating Co.*, 22 F.3d 546, 551 (4th Cir. 1994) (citation omitted). *See also Canon, Inc. v. GCC Int'l Ltd.*, 263 F. App'x 57, 62 (Fed. Cir. 2008) (“At the preliminary injunction stage, irreparable harm consists of harm that could not be sufficiently compensated by money damages or avoided by a later decision on the merits.”). The purpose of a preliminary injunction is “to preserve the legal interests of the parties against future infringement which may have market effects never fully compensable in money.” *Hybritech*, 849 F.2d at 1457. Generally, monetary damages are not an adequate remedy against future infringement of a patent. *Smith & Nephew, Inc. v. Synthes (U.S.A.)*, 466 F. Supp. 2d 978, 984 (W.D. Tenn. 2006).

As described below, the market impact of GE’s continued infringement of Hill-Rom’s patents will be extensive, likely irreversible, and not curable by money damages. GE is a direct competitor of Hill-Rom, and GE’s imminent sale of infringing products during the pendency of this lawsuit will not be compensable by the mere payment of damages. The market for the RTLS-based hand hygiene systems at issue here is in its most critical beginning stages, and by infringing Hill-Rom’s patents, GE is obtaining market share that may be impossible for Hill-Rom to recapture even when it ultimately prevails in this lawsuit. With each sale of its infringing product, GE captures a customer that is unlikely to purchase another RTLS-based hand hygiene system for up to 15 years. McMullin Decl. at ¶¶ 22-23. GE’s infringement is also damaging Hill-Rom’s reputation and may be suppressing the price that Hill-Rom’s products

would otherwise command. Hill-Rom is entitled to a preliminary injunction to stanch this ongoing and irreparable harm. *See Phillips v. Crown Cent. Petroleum Corp.*, 602 F.2d 616, 630 (4th Cir. 1979) (“A future injury of uncertain date and incalculable magnitude is irreparable harm, and protection from such an injury is a legitimate end of injunctive relief.”).

A. Without a Preliminary Injunction, Hill-Rom Will Permanently Lose the Opportunity to Capture Market Share in a Nascent Market in Which Its Long-Term Market Position Is Significantly Influenced by Initial Sales.

Numerous courts have recognized that infringement by a direct competitor in a nascent market constitutes injury so severe as to be irreparable and incapable of compensation in damages. For example, in *TiVo, Inc. v. EchoStar Communications Corp.*, TiVo sought a permanent injunction, alleging that EchoStar infringed its patents in the young market for digital video recorders (“DVRs”). 446 F. Supp. 2d 664 (E.D. Tex. 2006) *rev’d in part on other grounds*, 516 F.3d 1290 (Fed. Cir. 2008). In holding that TiVo had demonstrated irreparable harm, the court observed that “Defendants compete directly with Plaintiff—Defendants market their infringing products to potential DVR customers as an alternative to purchasing Plaintiff’s DVRs.” *Id.* at 669. The court found that “[t]he availability of the infringing products leads to loss of market share for Plaintiff’s products.” *Id.* It emphasized that the parties were competing in a new market, stating that “[l]oss of market share in this nascent market is a key consideration in finding that Plaintiff suffers irreparable harm[.]” *Id.* at 669-670.⁴ The Court continued,

⁴ Even in established markets, infringement by a direct competitor weighs heavily in favor of finding irreparable harm. *See, e.g., Systemation, Inc. v. Engel Indus., Inc.*, 194 F.3d 1331, 1999 WL 129640, *6 (Fed. Cir. 1999) (affirming preliminary injunction and holding that “los[s of] sales to a direct competitor” evinces irreparable harm); *Visto Corp. v. Seven Networks, Inc.*, 2:03-CV-333-TJW, 2006 WL 3741891, *4 (E.D. Tex. Dec. 19, 2006) (granting permanent injunction; “The parties to this case are direct competitors, and this fact weighs heavily in the court’s analysis. Intellectual property enjoys its highest value when it is asserted against a direct competitor in the plaintiff’s market.”); *Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, No. 3:06-CV-1105, 2011 WL 2927817, *10 (M.D. Pa. July 18, 2011) (granting preliminary

“Plaintiff is losing market share at a critical time in the market’s development, *market share that it will not have the same opportunity to capture once the market matures.*” *Id.* at 669-70 (emphasis added).⁵

Here, as in *TiVo*, the patentee and infringer are directly competing in a young and rapidly developing market with potential for significant growth in sales. *See* 446 F. Supp. 2d at 669; McMullin Decl. at ¶¶ 18, 21. In this type of market, winning large initial contracts with significant customers will significantly influence each competitor’s long-run market position. Reiff Decl. at ¶ 27. As in *TiVo*, “[t]he availability of [GE’s] infringing products leads to loss of market share for Plaintiff’s products.” 446 F. Supp. 2d at 669; Reiff Decl. at ¶¶ 23, 30-31 (sales lost to competitor harm market position).

injunction; “Each sale of a Bridgeport duplex connector likely deprives Arlington of market share, revenue, and brand recognition. . . . Although the parties may not be the only competitors, they are direct competitors, a factor of substantial weight in the irreparable injury analysis.”), *modified in part on other grounds*, 2011 WL 4916397, at *4-6 (M.D. Pa. Oct. 17, 2011).

⁵ A number of other courts have reached similar conclusions. *See, e.g., Butamax Advanced Biofuels LLC v. Gevo, Inc.*, 868 F. Supp. 2d 359, 374-75 (D. Del. 2012) *aff’d and remanded sub nom. Butamax Advanced Biofuels LLC v. Gevo, Inc.*, 486 F. App’x 883 (Fed. Cir. 2012) (concluding that irreparable harm would exist if defendants were infringing, “since the parties are direct competitors in an emergent market,” and noting that “as the first entrant into the marketplace, defendant would have advantages that include working with the best facilities and potential customers and being perceived as an innovator in the field.”); *Baker Hughes Inc. v. Nalco Co.*, 676 F. Supp. 2d 547, 554 (S.D. Tex. 2009) *aff’d*, 374 F. App’x 979 (Fed. Cir. 2010) (granting preliminary injunction where new market “consists of a small number of potential clients,” and “the parties are in direct competition for this business”); *Power-One, Inc. v. Artesyn Technologies, Inc.*, CIV. A. 2:05-CV-463, 2008 WL 1746636, at *1 n.1 (E.D. Tex. Apr. 11, 2008) *aff’d*, 599 F.3d 1343 (Fed. Cir. 2010) (granting permanent injunction; irreparable harm where patentee and infringer were direct competitors, infringing product “froze the market,” and the plaintiff “only recently created” the market at issue, “making the harm particularly acute”); *Hybritech*, 849 F.2d at 1456 (fact that patent helped patentee establish market position in field of new technology, in which the technology changed rapidly, weighed in favor of finding irreparable harm).

Moreover, Hill-Rom is losing market share at a critical stage of the market's development, and it will not have the same opportunity to capture that market share once the market matures. Reiff Decl. at ¶¶ 25-29. GE's continued infringement will give it unearned advantages, including working with some of the best facilities and potential customers, such as HCA. McMullin Decl. at ¶¶ 32, 35 (HCA has installed GE's infringing product); Reiff Decl. at ¶ 31 ("Winning or losing the HCA business will have long-term implications for Hill-Rom's market position."). Furthermore, the parties are direct competitors in a new market that currently consists of few potential clients, with one dominant potential customer, HCA. McMullin Decl. at ¶ 27 ("Presently, one of the most significant and prized customers in the market for RTLS-based hand hygiene systems is Hospital Corporation of America ('HCA'), which operates approximately 165 hospitals and 115 freestanding surgery centers throughout the country."). Without a preliminary injunction, "the market position Hill-Rom expected to achieve by marketing its patented technology is likely to suffer long-term impairment." Reiff Decl. at ¶ 37.

Further deepening the incalculable loss to Hill-Rom's market share if GE is not enjoined is the fact that the RTLS-based hand hygiene systems at issue require a high initial investment by the user, have a long life-cycle, and are costly to replace once installed. McMullin Decl. at ¶¶ 22-24, 26; Reiff Decl. at ¶¶ 27-29. Thus, each time GE sells an infringing product, Hill-Rom loses a corresponding share of the market for at least the life span of the product (and potentially permanently, due to the difficulty of displacing an incumbent supplier). *See* Reiff Decl. at ¶ 28. Lost market share is particularly damaging when the product at issue is expensive and infrequently replaced. *See Morris & Assocs., Inc. v. Cooling & Applied Tech., Inc.*, 5:09-CV-23-BR, 2010 WL 4484640, at *9 (E.D.N.C. July 30, 2010) (irreparable harm where alleged infringer competed with patentee, and product at issue was "large, custom, expensive, and designed to last

a significant lifetime of production;” concluding that preliminary injunction was warranted). “[O]nce a [customer] purchases one of these systems, it is unlikely they will reenter the market place for a significant number of years,” meaning that “each sale of equipment is the likely formation of a long-lasting business relationship.”⁶ *Id.*

Here, the harm is particularly acute because some of the Hill-Rom patents in suit will expire in 2020. Reiff Decl. at ¶ 36. The window of opportunity for Hill-Rom to realize the value of its patents is *now*. If GE displaces Hill-Rom for a full product cycle, the harm to Hill-Rom will be truly irreparable, because Hill-Rom will no longer have patent protection when the customer is next in the market for a new RTLS-based hand hygiene system. *Id.* Thus, the benefits that flow from making the first sale to a customer are particularly critical to Hill-Rom here. *See Morris & Assocs.*, 2010 WL 4484640, at *9.

Hill-Rom has demonstrated lost market share by submitting evidence of GE’s actual and threatened sales of infringing RTLS-based hand hygiene systems to one of the largest customers in the market, HCA. McMullin Decl. at ¶¶ 32, 35 (HCA has installed GE’s infringing product);

⁶ Even in markets that are not in their infancy and do not involve long-lasting, expensive products, lost market share strongly supports a finding of irreparable harm. *See i4i Ltd. P’ship v. Microsoft Corp.*, 598 F.3d 831, 861-62 (Fed. Cir. 2010) *aff’d*, 131 S. Ct. 2238, 180 L. Ed. 2d 131 (U.S. 2011) (irreparable harm where competitor’s infringement caused loss of market share and forced patentee to change its business strategy; affirming permanent injunction); *Purdue Pharma L.P. v. Boehringer Ingelheim GMBH*, 237 F.3d 1359, 1367-68 (Fed. Cir. 2001) (noting that patentee’s evidence of expected price erosion and loss of market position provided adequate evidence of irreparable harm; affirming preliminary injunction); *Polymer Technologies, Inc. v. Bridwell*, 103 F.3d 970, 975-76 (Fed. Cir. 1996) (vacating denial of preliminary injunction, finding that “[c]ompetitors change the marketplace. Years after infringement has begun, it may be impossible to restore a patentee’s (or an exclusive licensee’s) exclusive position by an award of damages and a permanent injunction.”); *Canon*, 263 F. App’x at 62 (affirming preliminary injunction: “As the trial court found, competition from Defendants will likely result in substantial price erosion of Canon’s patented product as well as loss of Canon’s market share. Due to the difficulty (if not impossibility) of determining the damages resulting from price erosion and loss of market share, an award of money damages would not be sufficient.”).

Reiff Decl. at ¶ 30 (“[W]here the patent-holder and the infringer are head-to-head competitors for key contracts, the losing firm’s potential sales generally flow to the contract winner.”). Hill-Rom and GE are the only companies from which HCA is considering purchasing RTLS-based hand hygiene systems. McMullin Decl. at ¶ 29. Thus, each sale to HCA of an infringing GE system directly deprives Hill-Rom of a sale.

Even in circumstances where there are multiple competitors, evidence of lost sales supports a finding of irreparable harm. *See Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1154 (Fed. Cir. 2011) (reversing denial of permanent injunction). In *Robert Bosch*, the defendant argued that the patentee’s lost market share was due to other competitors. *Id.* The court rejected that argument, pointing out that the defendant “secured the Wal-Mart account, which alone accounts for a substantial portion of the entire market.” *Id.* The patentee adequately proved lost market share by showing that “it previously secured the Wal-Mart account,” which was “circumstantial evidence that it would reclaim Wal-Mart’s business were Pylon enjoined.” *Id.* This case has at least the factual support present in the *Robert Bosch* case: both Hill-Rom and GE have placed RTLS-based hand hygiene systems at HCA. Both are credible suppliers, and Hill-Rom has been informed that HCA intends to purchase its hand hygiene systems from either Hill-Rom or GE. McMullin Decl. at ¶ 29. Thus, Hill-Rom has shown irreparable harm.

B. Without a Preliminary Injunction, Hill-Rom Will Lose the Opportunity to Form Long-Term Customer Relationships and Will Lose the Attendant Benefits of Those Relationships.

At issue here are not only initial sales of the hand hygiene systems, but also long-term harm to Hill-Rom resulting from the early entrant advantage. In finding irreparable harm, the *TiVo* court relied on the fact that “DVR customers . . . tend to remain customers of the company from which they obtain their first DVR.” 446 F. Supp. 2d at 670. Therefore, the court held that “the impact of Defendants’ continued infringement is shaping the market to Plaintiff’s

disadvantage and results in long-term customer loss.” *Id.* The harm resulting from the defendants’ shaping the market was “particularly key where, as is the case here, Plaintiff’s primary focus is on growing a customer base specifically around the product with which Defendants’ infringing product competes.” *Id.* For those reasons, the court held that “the full impact of Defendants’ infringement cannot be remedied by monetary damages.” *Id.*

The *Morris & Associates* court also recognized that because the relevant products were expensive and long-lasting, each sale would likely result in “a long-lasting business relationship.” 2010 WL 4484640, at *9. *See also Ticor Title Ins. Co. v. Cohen*, 173 F.3d 63, 69 (2d Cir. 1999) (finding irreparable harm because “it would be very difficult to calculate monetary damages that would successfully redress the loss of a relationship with a client that would produce an indeterminate amount of business in years to come” and affirming permanent injunction).

In the market for hand hygiene systems, each sale is likely to lead to a lasting customer relationship. Reiff Decl. at ¶ 29; McMullin Decl. at ¶ 25. The customer will rely on its supplier for advice and technical support over the years, strengthening the customer bond. Reiff Decl. at ¶ 29. This relationship will give the incumbent an inherent advantage over competitors when seeking to make future sales. Reiff Decl. at ¶ 29; McMullin Decl. at ¶¶ 24-26. In addition to the strengthened relationship, a customer may prefer to stick with the same supplier in the future because it is accustomed to using a particular system. Reiff Decl. at ¶¶ 28-29; McMullin Decl. at ¶ 24. For all of these reasons, Hill-Rom faces real and irreparable injury from lost customer relationships if GE’s infringement is permitted to continue during the course of this litigation.

C. In Addition to Lost Market Share, Hill-Rom Stands to Suffer Price Erosion and Lose Significant Ancillary Sales in the Absence of a Preliminary Injunction.

GE's infringement is likely to result in Hill-Rom losing substantial sales of related products that it would have made absent GE's infringement. McMullin Decl. at ¶¶ 44-46; Reiff Decl. at ¶¶ 33-34. Sales of Hill-Rom's RTLS-based hand hygiene systems are likely to lead to additional sales in several ways. First, Hill-Rom's and GE's hand hygiene systems operate through each firm's RTLS used for tracking and monitoring additional products beyond hand hygiene. Hill-Rom anticipates significant additional sales of its RTLS products if it successfully sells its related hand hygiene compliance system. McMullin Decl. at ¶¶ 20, 46. Second, Hill-Rom anticipates that each installation of its RTLS-based hand hygiene system will result in significant consulting revenue and long-term maintenance revenue. *Id.* at ¶ 45. Third, each sale of an RTLS-based hand hygiene system is likely to generate indirect sales of products that tie into the RTLS system, such as Hill-Rom's NurseCall, WatchChild, and hospital beds. *Id.* at ¶ 46. Not only is the volume of such lost sales likely to be significant, but the amount of lost associated sales is difficult to estimate, making money damages particularly inadequate. Reiff Decl. at ¶ 33. These types of lost sales contribute to the irreparable harm Hill-Rom faces, and warrant a preliminary injunction. *See Baker Hughes*, 676 F. Supp. 2d at 554 (irreparable harm where infringement harmed patentee's "ability to engage in the sale of functionally related products").

GE's sale of infringing products may also result in price erosion. "Direct competition between a patent-holder and an infringer or infringers can lead to a reduction in prices." Reiff Decl. at ¶ 30 n.25. As a result, not only does the patentee lose sales, but its sales likely would have occurred at higher prices. *Id.* This constitutes irreparable harm and warrants a preliminary

injunction. *See Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1382 (Fed. Cir. 2006) (price erosion was a basis for finding irreparable harm; affirming preliminary injunction).

D. Without a Preliminary Injunction, Hill-Rom Will Suffer Damage to Its Reputation and Good Will.

In addition to the tangible loss of revenue from sales and long-term market placement described above, GE’s sales of infringing products also threaten Hill-Rom’s reputation as an established supplier and innovator. “During the growth stage of a product, it is particularly crucial to be able to distinguish oneself from competitors,” including by “building the brand, expanding the customer base, and establishing one’s reputation and leadership in the market.” *Celsis In Vitro*, 664 F.3d at 931. When a competitor sells infringing products in the market, customers may not recognize the true innovator. *See id.*; *see also Bushnell, Inc. v. Brunton Co.*, 673 F. Supp. 2d 1241, 1263 (D. Kan. 2009) (irreparable harm shown where infringement damaged plaintiff’s “reputation as an innovator and producer of competitively priced quality products;” preliminary injunction granted); *Wald v. Mudhopper Oilfield Servs., Inc.*, CIV-04-1693-C, 2006 WL 2128851, at *5 (W.D. Okla. July 27, 2006) (plaintiffs demonstrated irreparable harm by showing “that they lost market share and the opportunity to maintain their own polymer stick . . . as the industry standard and that their reputation for innovation was damaged as a result” (internal quotation marks omitted; permanent injunction granted)).

In addition, customers often develop brand loyalty, and an infringer’s sales may hinder a patentee’s ability to develop customer good will. *QBAS Co., Ltd. v. C Walters Intercoastal Corp.*, 2010 WL 7785955, at *12–13 (C.D. Cal. 2010) (where “customer is likely to stick with a brand that the customer knows and trusts, . . . Plaintiffs’ inability to develop a consistent and loyal customer base due to Defendants’ competing product also shows irreparable harm;” preliminary injunction granted); *see also* Reiff Decl. at ¶ 28 (“once the customer chooses a

particular brand for its hand hygiene system, it then makes a long-term commitment to that brand by developing the infrastructure . . . and training associated with the brand”).

By selling competing products based on Hill-Rom’s groundbreaking inventions, GE’s ongoing infringement is damaging Hill-Rom’s reputation as an innovator. Reiff Decl. at ¶ 32 (“the loss of early sales to GE Healthcare harms Hill-Rom’s reputation as an innovator, undercutting Hill-Rom’s ability to distinguish itself from competitors”). Moreover, each of GE’s infringing sales deprives Hill-Rom of the ability to cultivate a long-term customer relationship. *See id.* at ¶ 29. Because GE’s threatened infringement also will impair Hill-Rom’s reputation and status as innovator in the field, it is additional irreparable harm that must be prevented with a preliminary injunction.

E. Absent a Preliminary Injunction, a Permanent Injunction or Damages Award Will Not Fully Compensate Hill-Rom for GE’s Infringement.

In response to a request for a preliminary injunction, the Court is right to ask “Why now?” The answer: without immediate relief, Hill-Rom will be forced to wait until the end of this litigation, which likely will not arrive until sometime in 2015. But by then, a “significant portion of the potential customer base” – and HCA in particular – may “be committed to GE Healthcare’s hand hygiene and associated RTLS products.” Reiff Decl. at ¶ 35; *see also* McMullin Decl. at ¶ 24. An injunction at that point is unlikely to restore Hill-Rom to the market position it would have occupied absent GE’s infringement. *Id.* Money damages at the conclusion of litigation also will be inadequate to restore Hill-Rom’s lost market position. Estimated lost profits “[a]t best . . . would likely capture the direct lost volume and possible price erosion,” but would not necessarily account for lost indirect sales and business opportunities that Hill-Rom would have enjoyed absent harm to its market position. Reiff Decl. at ¶ 38. Damages cannot restore Hill-Rom’s market position. *See id.* In contrast, a preliminary injunction will

prevent both the financial losses and the harm to market position. *Id.* at ¶ 39. Because money damages would not adequately remedy the harm that Hill-Rom will suffer, a preliminary injunction is warranted. *Canon, Inc.*, 263 F. App'x at 62.

Because GE's conduct will lead to irreparable harm, Hill-Rom is entitled to a preliminary injunction to maintain the status quo during the pendency of this action. *See P.N.A. Constr. Techs., Inc. v. McTech Group, Inc.*, 414 F. Supp. 2d 1228, 1244 (N.D. Ga. 2006) ("A principal purpose of preliminary injunctive relief is to maintain the status quo."). "Status quo" does not mean, however, that an infringer is permitted to continue infringing until the litigation is resolved. *Atlas Powder Co. v. Ireco Chems.*, 773 F.2d 1230, 1231 (Fed. Cir. 1985) ("[Defendant] would have us maintain the status quo by allowing it to continue the alleged infringements at the rate they occurred when the suit was filed, even though the assessment of likelihood of success has shown that such acts would probably be held unlawful. Such a proposition is its own refutation and no other is necessary."). Permitting the infringer to continue the wrong "is in no realistic sense maintaining the status quo." *Id.* at 1231-32.

The status quo to be preserved here is Hill-Rom's exclusive right to make, have made, import, use, sell, or offer for sale hand hygiene systems covered by its presumptively valid patents. For the reasons described above, Hill-Rom will be irreparably harmed if GE is permitted to continue selling its infringing AgileTrac systems while this matter is being litigated. Accordingly, GE should be preliminarily enjoined from making further illegal sales of its AgileTrac products. *See id.*

III. THE BALANCE OF HARDSHIPS FAVORS HILL-ROM.

The balance of hardships tips decidedly in favor of granting a preliminary injunction. In evaluating the balance of hardships, a "court must balance the harm that will occur to the moving party from the denial of the preliminary injunction with the harm that the non-moving party will

incur if the injunction is granted.” *Hybritech*, 849 F.2d at 1457. Any non-compensable harm that may be suffered by GE due to a wrongful preliminary injunction is clearly outweighed by the significant harm that Hill-Rom will endure in the absence of a preliminary injunction.

If the Court does not enter a preliminary injunction, the consequences for Hill-Rom will be severe. Hill-Rom is attempting to capture market share in a new market, but has been placed at a disadvantage by GE’s infringing conduct and will lose substantial further ground if that infringement is not stopped immediately. With each sale of GE’s infringing product, Hill-Rom suffers a loss of market share, customer relationship, and reputation, which irreparably harms Hill-Rom as it attempts to gain a foothold in this emergent market. Reiff Decl. at ¶¶ 29-32. Hill-Rom is already aware of at least one sale it has lost in the hand hygiene system market due to GE’s sales of infringing products to HCA. McMullin Decl. at ¶ 37. Additional sales will only lengthen the improper head-start that GE has taken, further diminishing Hill-Rom’s likely long-term market share. *See* Reiff Decl. at ¶¶ 38-39. Because the turnover for the systems at issue is so infrequent, and the customer relationship so important, the harm caused by every sale of GE’s infringing product is particularly acute. *Id.* at ¶¶ 22-23, 36.

In contrast, GE will not be meaningfully harmed by the entry of a preliminary injunction enjoining its sales of the AgileTrac product. GE sells many other products, so any loss of sales it experiences due to a preliminary injunction will not significantly harm it. *See Acumed LLC v. Stryker Corp.*, 551 F.3d 1323, 1329-30 (Fed. Cir. 2008) (balance of hardships favored plaintiff where, *inter alia*, infringing product represented “only a small portion” of defendant’s sales). In 2013, the RTLS-based hand hygiene market involved sales of approximately \$5 million. McMullin Decl. at ¶ 16. GE amasses \$146 billion per year in annual revenue from a diverse range of products and services. *See* General Electric Co., Annual Report (Form 10-K) at 3, 28

(Feb. 27, 2014). Even if GE captured the entire market in 2013 and lost those sales as a result of the requested preliminary injunction, the lost revenue would represent a negligible 0.0034% of GE’s 2013 revenue. *See id.* at 3.

In any event, GE cannot be heard to complain of hardship, because any hardship it may suffer would result from its own decision to market a product infringing Hill-Rom’s patents. *See Pfizer, Inc. v. Teva Pharm., USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005) (“Simply put, an alleged infringer’s loss of market share and customer relationships, without more, does not rise to the level necessary to overcome the loss of exclusivity experienced by a patent owner due to infringing conduct.”). An infringer’s self-inflicted hardship from the calculated risk taken in selling an infringing product deserves no weight in the balance of the hardships. *See Sanofi-Synthelabo*, 470 F.3d at 1383 (rejecting infringer’s hardship claim where “harms were almost entirely preventable” and were the result of its own calculated risk to launch its product prejudgment); *see also Augat, Inc. v. John Mezzalingua Assocs., Inc.*, 642 F. Supp. 506, 509 (N.D.N.Y. 1986) (“To the extent the preliminary injunction poses a hardship to defendant because it has become excessively dependent on sales of its coaxial connector this poses no bar to the issuance of an injunction where it appears that these sales infringe plaintiff’s patent rights.”). Indeed, even where a preliminary injunction would put the infringer out of business—which is far from the case here—that fact “does not control the balance of hardships factor.” *Aria Diagnostics, Inc. v. Sequenom, Inc.*, 726 F.3d 1296, 1305 (Fed. Cir. 2013).

IV. THE PUBLIC INTEREST FAVORS A PRELIMINARY INJUNCTION.

The public interest favors granting a preliminary injunction in this case. Generally, it is in the public interest to enforce patents to encourage others to invent and utilize the patent system. *Sanofi-Synthelabo*, 470 F.3d at 1383 (The Federal Circuit has “long acknowledged the importance of the patent system in encouraging innovation. Indeed, the encouragement of

investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude.”). Hill-Rom properly sought and was granted multiple patents for its hand hygiene systems and methods. It is entitled to the Court’s protection of those patents. The public interest will be served by issuing a preliminary injunction, because “[t]here is a public interest in enforcing the protections secured by valid patents.” *Techtronic Indus. Co., Ltd. v. Chevron Holdings Ltd.*, 395 F. Supp. 2d 720, 737 (N.D. Ill. 2005) (citing *Hybritech*, 849 F.2d at 1458). Furthermore, the Federal Circuit has consistently held that absent any other relevant concerns, the public is best served by enforcing patents that are likely valid and infringed. *See, e.g.*, *Sandoz*, 544 F.3d at 1362; *see also Augat, Inc. v. John Mezzalingua Assocs., Inc.*, 642 F. Supp. 506, 509 (N.D.N.Y. 1986) (“The public interest in a patent case is strongly weighted toward protecting the rights of patent holders.”).

There are additional reasons why the public interest favors granting a preliminary injunction here. Specifically, there is a strong public interest in encouraging the sort of investment Hill-Rom has made in innovative health care systems and products. In a similar case, the court held that there is a particular public interest in “provid[ing] incentive to the innovative drug companies to continue costly development efforts.” *Sanofi-Synthelabo*, 470 F.3d at 1383-84. So too does the public benefit from providing incentive for companies such as Hill-Rom to continue investing in products such as its hand hygiene system, which addresses HAIs, a serious and difficult health problem in America’s hospitals. McMullin Decl. at ¶ 8. According to the Center for Disease Control and Prevention, there were approximately 722,000 HAIs reported in U.S. acute care hospitals in 2011, resulting in approximately 75,000 deaths. *Id.* at ¶ 2. Proper hand hygiene is one of the most effective means of decreasing the number of HAIs, and Hill-

Rom's patented RTLS-based hand hygiene system is designed specifically to reduce HAIs. *Id.* at ¶¶ 2-3, 8.

Hill-Rom spent many years developing its innovative, RTLS-based hand hygiene system as a way of ensuring compliance with hand hygiene best practices and combating HAI. McMullin Decl. at ¶¶ 8, 10. Hill-Rom sought and obtained patent protection for its groundbreaking inventions in this arena. GE has misappropriated that technology and is currently profiting from it, enjoying the fruits of Hill-Rom's labor without having made the investment. Enforcing the patent rights of health care innovators such as Hill-Rom is critical to protecting the important public interest in health care innovation. *See Sanofi-Synthelabo*, 470 F.3d at 1383-84; *Celsis In Vitro, Inc.*, 664 F.3d at 932 (the incentive to invest in drug research and development “would be adversely affected by taking market benefits away from the patentee and giving them to the accused infringer”). Moreover, the public interest will not be harmed by enjoining GE’s infringing product. Hill-Rom’s RTLS-based hand hygiene product is commercially available, meaning that an injunction will not deprive any hospital or other customer of the opportunity to adopt an RTLS-based hand hygiene system. *See Celsis in Vitro*, 664 F.3d at 932 (“both [the infringer] and [the patentee] sell the same products and are in direct competition,” so “the public can obtain the products from [the patentee]”). For these reasons, a preliminary injunction is in the public interest.

CONCLUSION

Hill-Rom invested many years and significant expense developing its innovative hand hygiene compliance system, which squarely addresses one of the most pressing public health problems: healthcare-associated infections. Hill-Rom now faces the threat of irreparable harm resulting from GE’s sale of infringing systems in direct competition with Hill-Rom. Hill-Rom not only faces lost sales in the near-term, but GE’s infringement also threatens to permanently

diminish Hill-Rom's market position. Hill-Rom is likely to show infringement because each of the claim elements is found in GE's infringing products. The balance of the hardships favors Hill-Rom as well. GE enjoys \$146 billion in annual revenue and will not be harmed by a preliminary injunction in this action. Finally, the public interest calls for a preliminary injunction in order to protect the patent system and encourage innovation and investment in critical healthcare areas such as hand hygiene. Accordingly, Hill-Rom respectfully requests that the Court grant its motion and enter an order preliminarily enjoining GE from marketing or selling its infringing products.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 8, 2014, I will electronically file the foregoing with the Clerk of the Court using the CM/ECF system, and will forward copies of the foregoing pleading by private process server to the following:

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